

Application No. 08/499,423

REMARKS

I. PRELIMINARY REMARKS

Claims 1, 3-7, 9-33, 35, 42-44, 46-66, 74-77, 79-88, and 91-97 are pending in the application. Claim 35 is amended to change its dependency in response to an objection in the previous Office Action. Claims 79-81 are now canceled.

Independent claims 1, 33 and 42 are currently amended to address various issues; dependent claims 64 and 84 are amended correspondingly. Basis for the amendment directed to the at least 100% increase in circumference from the first circumference to the second circumference is at p. 6, lines 20-29 (first circumference corresponding to 3.5mm tube diameter, second circumference corresponding to 8mm tube diameter), Example 1 (see p. 15, lines 19-22 and 30-32; first circumference corresponding to 3.2mm tube diameter, second circumference corresponding to 8mm tube diameter); see additionally Example 2 (3.2mm diameter to 10mm diameter), Example 3 (3.7mm diameter to 8mm diameter), Example 5 (3.6mm diameter to 8mm diameter), Example 8 (3.2mm diameter to 10mm diameter). Basis for the "designed range of operating pressures" amendment is at p.3, line 32 to p. 4, line 4.

Additionally, the preamble of most dependent claims is amended for consistency with the claims from which they depend by replacing 'tube' with 'article.' In claims 64-66 and 84 are also amended for consistency with the claims from which they depend by replacing 'internal pressure' with 'the circumferentially distending force.'

II. APPLICANTS' INVENTION

The present invention relates to a porous polytetrafluoroethylene tube covered by one or more layers of porous polytetrafluoroethylene film, wherein the film-covered tube circumferentially distends from a first circumference upon the application of a circumferentially distending force such as applied by an internal pressure. The film-covered tube exhibits minimal recoil following the removal of the circumferentially distending force. The porous polytetrafluoroethylene film-covered tube has a second circumference that is at least 100% larger than the first circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The porous polytetrafluoroethylene film-covered tube itself provides the circumferential distensibility up to the limit, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels,

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particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The inventive film-covered tube is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilatation of the blood vessel into which it is fitted.

III. OBJECTION TO CLAIMS 35, 79-81.

These claims are objected to because they depended from previously canceled claims. Claim 35 is amended to correct the dependency; claims 67-69 are canceled herein.

IV. REJECTION OF CLAIMS 86-88, 91 AND 95-97 UNDER 35 USC 102(e) AS BEING ANTICIPATED BY GOLDFARB, US 6,436,135.

The Examiner states with regard to these rejected claims that Goldfarb discloses a PTFE tube that is fully capable of having its circumference increase with the application of blood pressure. While the tube of Goldfarb may increase in circumference over time, it does not increase in circumference in response to the *initial* application of blood pressure as required by the instant claims. This tube is commercially available as the Impira Distaflo® Bypass Graft (C.R. Bard, Murray Hill, NJ) for use as a peripheral bypass vascular graft. If this product increased in diameter upon exposure, it would not be capable of use as a conventional graft that must function as a fixed-diameter blood conduit. Indeed, if this product increased in circumference upon initial exposure to blood pressure, it would shortly fail catastrophically by rupture, having no 'second circumference' as taught by the instant specification. Goldfarb states (col. 9, lines 25-27) that "...the basic prosthetic structure may be made various lengths and in diameters up to approximately 40 millimeters without affecting the structural integrity or operativeness of the graft."

Regarding recoil (claims 91 and 95-97), the Examiner is correct that recoil is inherent in the tubes of the prior art. The claim relates to a tube showing less recoil than the recoil inherent in the prior art, a feature resulting from a process step performed on the inventive tubes and not taught or suggested in any way by the prior art. This lack of recoil (and the importance thereof) is described in the specification at p. 4, lines 16-25 and p. 7, line 28 to p. 8, line 27

Examples 1-3 of the instant specification teach in detail how the reduction in recoil is achieved (note particularly description at p. 15, lines 14-22 relating to steps 7-9 of the flow chart of

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Figure 4). None of the cited references teach or suggest any such method or result. Further, Example 3, as a control, specifically describes the recoil inherent in the Goldfarb (Impra) tube; see p. 17, line 35 to p. 18, line 8.

Accordingly, these claims are not anticipated by Goldfarb.

V. REJECTION OF CLAIMS 1, 3-7, 9-17, 19-31, 33, 35, 42-44, 46-66, 74-77, 79-88, AND 91-97 UNDER 35 USC 102(e) AS BEING ANTICIPATED BY SHANNON et al., US 5,641,373.

The Examiner states that Shannon teaches tube of porous PTFE provided with layers of porous PTFE material, and further discloses the microstructure of nodes and fibrils, the relevant wall thickness, use with a stent, and that "...since the graft is inherently capable of expanding to a second circumference, it is fully capable of having a tapered profile upon expansion in a tapered vessel."

Applicants respectfully disagree with regard to the Examiner's position, particularly with regard to the claims as amended herein. There is simply no evidence in the teachings of Shannon et al. that the graft taught therein is capable of the claimed performance. As such, the present invention is not anticipated by Shannon et al. There is no suggestion to make an ePTFE tube having a covering of ePTFE film that possesses a first circumference that may be increased to a second circumference at least 100% larger than the first circumference by the application of an internal pressure, and not change substantially beyond the second circumference with further increasing pressure if used within a designed range of operating pressures. Further, regarding dependent claims directed to lack of recoil following release of the internal pressure, Shannon et al. again make no suggestion as to how that lack of recoil might be provided.

VI. REJECTION OF CLAIMS 18 AND 32 UNDER 35 USC 103(a) AS UNPATENTABLE OVER SHANNON et al., US 5,641,373 IN VIEW OF HUGHES et al., US 4,728,328.

Goldfarb and Shannon et al. are addressed above; Hughes et al. only add the disclosure of a graft having three ends (bifurcated). Claims 18 and 32, as ultimately dependent to claim 1, are patentable as argued above.

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VII. REJECTION OF CLAIMS 92-94 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER GOLDFARB, US 6,436,135.

As described above, the property of excessive recoil is inherent in the ePTFE tube described by Goldfarb; note, again, the description of the recoil of this tube (used as a comparative control) in Example 3 (p. 17, line 35 to p. 18, line 8). Likewise, the value of a lack of recoil has also been described above. Goldfarb clearly does not teach or suggest either a graft having a lack of recoil or any method by which such an article might be achieved.

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,



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